

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
10 November 2005 (10.11.2005)

PCT

(10) International Publication Number
WO 2005/105317 A2

(51) International Patent Classification⁷: **B05B 5/00**
(21) International Application Number:
PCT/GB2005/001550
(22) International Filing Date: 25 April 2005 (25.04.2005)
(25) Filing Language: English
(26) Publication Language: English
(30) Priority Data:
0409381.1 27 April 2004 (27.04.2004) GB

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (for all designated States except US): **PHOQUS PHARMACEUTICALS LIMITED** [GB/GB]; 10 Kings Hill Avenue, West Malling, Kent ME19 4PQ (GB).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **HALLETT, Martin, David** [GB/GB]; 62 Park Avenue, Northfleet, Gravesend, Kent DA11 8DS (GB).

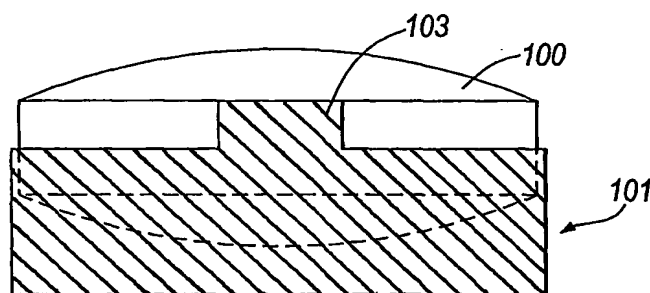
Published:

— without international search report and to be republished upon receipt of that report

(74) Agents: **BARDO, Julian, Eason et al.**; Abel & Imray, 20 Red Lion Street, London WC1R 4PQ (GB).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ELECTROSTATIC APPLICATION OF POWDER MATERIAL TO SOLID DOSAGE FORMS



(57) Abstract: A method of applying coating material onto part of a side of a solid dosage form (100) includes the steps of providing a source of coating material and a support assembly supporting the solid dosage form (100), the support assembly including a shield (101), arranging the solid dosage form (100) relative to the shield (101) with a forward boundary edge of the shield (101) extending around and closely surrounding the side of the solid dosage form (100), and applying coating material to the solid dosage form (100). The boundary edge of the shield has a projecting portion (103) such that the rearward limit of the exposed portion of the side of the solid dosage form (100) curves around the solid dosage form. A solid dosage form produced by the method and an apparatus for carrying out the method are also described.

WO 2005/105317 A2

BEST AVAILABLE COPY

Electrostatic Application of Powder Material
to Solid Dosage Forms

The present invention relates to a method and
5 apparatus for the application of a coating material onto a
solid dosage form, and to a solid dosage form having a
coating layer. The invention relates more particularly,
but not exclusively, to cases where the solid dosage form
is a pharmaceutical solid dosage form and to cases where
10 the coating material is a powder material and is applied
electrostatically.

A "solid dosage form" can be formed from any solid
material that can be apportioned into individual units; it
may be, but is not necessarily, an oral dosage form.
15 Examples of pharmaceutical solid dosage forms include
pharmaceutical tablets, pharmaceutical pessaries,
pharmaceutical bougies and pharmaceutical suppositories.
The term "pharmaceutical tablet" should be interpreted as
covering all pharmaceutical products which are to be taken
20 orally, including pressed tablets, pellets, capsules and
spherules. Examples of non-pharmaceutical solid dosage
forms include items of confectionery and washing detergent
tablets.

The electrostatic application of powder material to
25 solid dosage forms is known. In one technique, described
in WO 96/35516 powder material is applied onto
pharmaceutical tablets while the tablets are moving on a
drum past a source of the powder material. The tablets are

- 2 -

supported in cupped receptacles on a first drum and all the exposed areas of the tablets are coated as they pass the source of powder material. Subsequently the tablets are transferred onto a second drum where they are supported
5 again in cupped receptacles but in the opposite orientation to that on the first drum so that areas of the tablets not exposed on the first drum are now exposed and vice versa. In that way the whole of each tablet is coated following its passage around both drums.

10 In WO 03/061841 an electrically conducting cylindrical shield is provided extending closely around the solid dosage form to create a physical and electrostatic barrier to the powder. By providing such a shield it becomes possible to coat a forward part of the solid dosage form
15 uniformly as far as a limit defined by the shield, with substantially no coating taking place to the rear of the shield. Thus a well defined limit to the coating can be obtained.

In certain applications it can be desirable to leave a
20 portion of the side of a tablet uncoated. For example, such an uncoated portion may enable the rate of drug release from the solid dosage form to be controlled or it may increase the rate of disintegration of the dosage form. In such a case it is commonly desirable for only a
25 relatively small area to be left uncoated and for the size of that area to be controlled to a reasonable degree of accuracy.

- 3 -

According to the invention there is provided a method of applying coating material onto part of a side of a solid dosage form, the method including the following steps:

providing a source of coating material and a support
5 assembly supporting the solid dosage form, the support assembly including a shield,

arranging the solid dosage form relative to the shield with a forward boundary edge of the shield extending around and closely surrounding the side of the solid dosage form,
10 and

applying coating material to the solid dosage form from the source, the boundary edge of the shield defining a rearward limit of an exposed portion of the side of the solid dosage form onto which coating material is applied,
15 wherein the boundary edge of the shield has projecting and recessed portions arranged such that the rearward limit of the exposed portion of the side of the solid dosage form varies around the solid dosage form.

By providing a shield with a boundary edge of the kind
20 defined above it becomes possible, after the completion of a second application of coating material, to provide a solid dosage form which is fully coated on its side in a region corresponding to a recessed portion of the shield but has a gap in its coating in a region corresponding to a
25 projecting portion of the shield. Thus the solid dosage form can be provided with one or more uncoated regions, those uncoated regions having a circumferential extent determined by the circumferential extent of the projecting

- 4 -

portion of the shield. If it is desired for functional reasons to have a relatively small uncoated region, that can be achieved by having a projecting portion of the shield that is of relatively small circumferential extent and the dimension of the uncoated region in the forward/rearward direction does not have to be especially small. That is advantageous because it is difficult to avoid some variation in that dimension and, if the dimension were very small, then even a small variation could have a significant effect on the overall size of the uncoated region. As well as or instead of providing functional advantages of the kind indicated above, the invention makes it possible to produce solid dosage forms with any of a wide variety of patterns on their sides. That may enable an especially attractive solid dosage form to be produced.

Where reference is made herein to an "uncoated" region it should be understood that the region is one where a coating present in a neighbouring region is absent. It is possible that the "uncoated" region will have some other coating applied before or after the coating in the neighbouring region. For example, an overcoating might be applied over all of the solid dosage form after carrying out the method of the invention, or an undercoating might be applied over all of the solid dosage form before carrying out the method of the invention.

The shape of the opening defined by the shield, in which opening the solid dosage form is received, is

- 5 -

preferably selected according to the shape of the solid dosage form, with the shield conforming to the outline shape of the side of the solid dosage form. Often that outline shape will be circular and in that case the shield preferably defines a circular opening, but it will be appreciated that other outline shapes are also possible, including, for example, an oval shape, in which case the shield preferably defines an oval opening. The shield preferably has a cylindrical part defining a cylindrical opening for accommodating the solid dosage form. The cylindrical opening may be of circular cross-section but, as explained above, may also have other cross-sectional shapes, for example an oval shape. The shield may consist substantially entirely of the cylindrical part but there may also be another part extending radially outwardly from the cylindrical part. The length of the cylindrical part of the shield may be relatively long, but it is preferred that the length is less than the depth of the solid dosage form, measured as the maximum separation between the front and rear faces of the solid dosage form; furthermore it is preferred that the length is substantially shorter than said depth of the solid dosage form; preferably the length is less than one third of said depth.

Depending upon the size and pattern of the uncoated region which it is desired to generate, it will often be desirable for the boundary edge of the shield to have a single projecting portion. In that case the remainder of the boundary edge of the shield may define a single

- 6 -

recessed portion. Alternatively the shield may have a plurality of projecting portions and a plurality of recessed portions. It will be understood that the terms "projecting" and "recessed" are used in a relative sense so that for example the "recessed portion" may simply be a portion that projects less than the "projecting portion".

The shape of the projecting and recessed portions may be chosen according to whatever functional and/or aesthetic characteristics are required. For example parts of the boundary edge of the shield may be straight and/or curved.

The boundary edge may be crenellated form. The projecting portion of the boundary edge may be of a curved shape, which may be part-circular, for example, semi-circular. The projecting portion may alternatively be of angular shape, for example, of rectangular or triangular shape. As described below, the solid dosage form may be coated more than once and consequently a combination of uncoated regions created. In that way, the solid dosage form may have uncoated regions of round (oval or circular) or diamond shape. Thus the method of the invention may include the further step of applying further coating material to at least a part of the shielded portion of the solid dosage form.

When further coating is subsequently applied, that is preferably achieved by a method including the following steps:

- 7 -

providing a source of further coating material and a support assembly for supporting the solid dosage form, the support assembly including a shield,

arranging the solid dosage form relative to the shield
5 in a new arrangement with a forward boundary edge of the shield extending around and closely surrounding the side of the solid dosage form and with the solid dosage form inverted such that at least some of the portion of the side of the solid dosage form to which coating material was
10 previously applied is to the rear of the forward boundary edge of the shield and is thereby shielded, and

applying the further coating material to the solid dosage form from the source, the forward boundary edge of the shield defining a rearward limit of an exposed portion
15 of the side onto which the further coating material is applied, the rearward limit extending rearwardly as far as a previously coated region of the side in at least one position around the boundary edge but not in at least another position around the boundary edge, whereby the side
20 of the solid dosage form in said at least another position remains uncoated.

Depending upon the shape of the uncoated region(s) required, the boundary edge of the shield used in the application of the further coating material may have a
25 straight edge or it may have projecting and recessed portions arranged such that the rearward limit of the exposed portion of the side of the solid dosage form varies around the solid dosage form. The variation in the

- 8 -

rearward limit of the further coating material applied is preferably matched to the variation in the rearward limit of the previously applied coating material. Of course in the case where a shield with a straight boundary edge is used in the application of a layer of coating material, that layer may be applied before or after the other layer.

Whilst it is within the scope of the invention for the coating material to be applied by any appropriate technique, it is an especially preferred feature of the invention that the coating material is applied electrostatically. The coating material is therefore preferably charged. The solid dosage form is preferably supported on the support assembly with a front face in the vicinity of the source of coating material and facing the source of coating material. The support assembly preferably includes an electrically conducting member in the vicinity of the rear face of the solid dosage form. The shield is preferably electrically conducting. A potential difference is preferably created between the source of coating material and the electrically conducting member and the shield is preferably maintained at a potential more similar to that of the source of coating material than to that of the electrically conducting member.

The step of creating a potential difference between the source of powder material and the electrically conducting member of the support assembly may comprise the step of providing an electrically conducting roller at the

- 9 -

powder source and applying a potential difference between the electrically conducting member of the support assembly and the electrically conducting roller at the powder source.

- 5 The potentials at which the electrically conducting shield and the source of powder material (preferably the electrically conducting roller) are preferably of the same sign and may be substantially the same.

- 10 The electrically conducting member may be electrically charged (to a potential substantially different and preferably of opposite sign to the powder source), but is preferably maintained at earth potential.

- 15 The potential difference created between the source of powder material and the electrically conducting member preferably includes a bias voltage that is a steady DC voltage. The polarity of the bias voltage is chosen according to whether the powder is positively or negatively charged, which in turn is dependent upon the powder and/or the charging process employed: for negatively charged
20 powders the bias voltage is negative and for positively charged powders it is positive, the bias voltage being defined as positive when the potential at the source of powder material is greater than the potential at the solid dosage form and vice versa. Preferably an alternating
25 voltage, which is preferably substantially higher than the DC voltage, is superimposed on the initial bias voltage. The presence of such an alternating voltage serves to mobilise the charged powder reducing any tendency of the

- 10 -

powder particles to adhere to a surface on which they are carried; in a described embodiment that surface is the periphery of a roller. The alternating voltage preferably has a peak to peak value greater than, and more preferably
5 more than twice, the peak value of the DC bias voltage. For example the alternating voltage may have a peak to peak value of the order of 5kV. The sum of the DC bias voltage and one half of the peak to peak alternating voltage must not be so great that the potential difference causes
10 breakdown of the air. The frequency of the alternating voltage is preferably in the range of 1 to 15kHz.

Preferably the electrically conducting shield comprises an electrically conducting member covered by a layer of insulating material. The provision of a layer of
15 insulating material, which is preferably thin, prevents accidental electrical contact being made between the solid dosage form and the shield.

The spacing between the boundary edge of the shield and the solid dosage form is preferably small and may be
20 less than 1mm. The spacing is preferably uniform around the whole of the circumference of the solid dosage form.

Preferably a plurality of solid dosage forms are supported on the support assembly, a plurality of shields, each disposed closely around a respective one of the solid
25 dosage forms are provided and the support assembly is moved relative to the source of coating material to bring in turn each of the solid dosage forms into the vicinity of the source of coating material. In such a case the shields may

- 11 -

all be part of a common shield assembly which may be mounted on a base part of the support assembly.

Whilst the coating material may be a liquid material it is preferably a powder material.

5 Preferably the coating material applied to the solid dosage form is subsequently treated to fix it on the solid dosage form. The treatment of the coating material to fix it to the solid dosage form preferably involves a heating step, preferably using infra red radiation, but other forms
10 of heating such as convection, conduction or induction may be used. The coating material should be heated to a temperature above its softening point, and then allowed to cool until solid. It is important to control the amount of heat applied to avoid degradation of the coating material
15 and/or the solid dosage form. The amount of heat required may be reduced by applying pressure to the coating material. Alternatively, the coating material may include a polymer which is cured during the treatment, for example, by irradiation with energy in the gamma, ultra violet or
20 radio frequency bands.

The coating material may include a biologically active material, that is, a material which increases or decreases the rate of a process in a biological environment. The biologically active material may be one which is
25 physiologically active.

The solid dosage form may be a domed tablet having a pair of opposite domed end faces joined by a cylindrical side wall. In such a case, the coating material may be

- 12 -

applied uniformly over the whole of one domed end face of the tablet and a forward part of the cylindrical side wall, the remaining, rearward, part of the cylindrical side wall being shielded from the application of powder by the

5 shield. The solid dosage form may, more particularly, be an oral dosage form and/or a pharmaceutical dosage form, for example a pharmaceutical tablet.

Whilst it is preferred to use a shield to create the uncoated regions on the solid dosage form, according to
10 another aspect of the invention other techniques may be employed to provide the uncoated regions. Thus in another aspect of the invention there is provided a method of applying coating material onto a side of a solid dosage form, the method including the following steps:

15 applying a first coating layer to a forward part of the side of the solid dosage form,

applying a second coating layer to a rearward part of the side of the solid dosage form,

wherein the first and second coating layers overlap in
20 at least one region of the side of the solid dosage form but are spaced apart in at least one other region of the side of the solid dosage form to leave an uncoated region between them.

The side of the solid dosage form may be of generally
25 cylindrical shape. Preferably the side of the solid dosage form surrounded by the shield is of round shape and it may be of substantially circular shape. The solid dosage form may also be of a lozenge shape, for example the shape of a

- 13 -

capsule or of a tablet having a similar shape in plan view to a capsule. The solid dosage form may have domed end faces.

Such a method may also include any of the features
5 described above with reference to the first aspect of the method of the invention.

The present invention further provides a solid dosage form including a side extending around the solid dosage form and having at least two coating layers each of the
10 layers extending around the solid dosage form with layers overlapping in at least one region and being spaced apart in at least one other region to leave an uncoated region between them.

The side of the solid dosage form may be of generally
15 cylindrical shape.

One of the coating layers may have a straight boundary edge overlapped in at least one region by the other coating layer.

There may be a single uncoated region or a plurality
20 of uncoated regions may be left, which may be evenly spaced around the solid dosage form.

The or each uncoated region may be of various shapes, for example, of generally round shape or of generally rectangular shape.

25 In many applications it is desirable that said at least one uncoated region occupies only a minor part of the perimeter of the solid dosage form.

- 14 -

The solid dosage form may be made by a method as defined above, and may have any of the features that may arise from carrying out a method as defined above whether or not the said dosage form is made by such a method.

5 The present invention further provides an apparatus for applying coating material onto part of a side of a solid dosage form, the apparatus including:

 a source of coating material, and

 a support assembly for supporting the solid dosage
10 form in a position where the part of the side wall onto which coating material is to be applied is able to receive the coating material,

 wherein the support assembly includes a shield for extending around and closely surrounding the side wall of
15 the solid dosage form, the shield having a boundary edge for defining a rearward limit of an exposed portion of the side of the solid dosage form onto which coating material is to be applied, the boundary edge having projecting and recessed portions arranged such that the rearward limit of
20 the exposed portion of the side of the solid dosage form varies around the solid dosage form.

 The apparatus may be of a form suitable for carrying out any of the methods defined above.

 It should be understood that features described above
25 with reference to the method or product of the invention may also, where appropriate be present in the apparatus of the invention and vice versa.

- 15 -

By way of example certain embodiments of the invention will now be described with reference to the accompanying drawings, of which:

5 Fig. 1 is a schematic sectional view of an apparatus for electrostatically applying a powder material to a solid dosage form,

Fig. 2 is an enlarged sectional view of a part of the apparatus including a shield assembly,

10 Fig. 2A is a schematic plan view of the part of the apparatus shown in Fig. 2,

Fig. 3a is a perspective view of a cylindrical crenellated shield suitable for use in an embodiment of the invention,

15 Fig. 3b is a side view of a tablet surrounded by the shield of Fig. 3a and shown in the position it occupies during coating of a tablet with a first layer of coating material,

20 Fig. 3c is a side view of the tablet shown in Fig. 3b after coating with two layers of coating material,

Fig. 4a is a perspective view of another form of cylindrical crenellated shield suitable for use in another embodiment of the invention,

25 Fig. 4b is a side view of a tablet with the shield of Fig. 4a shown in the position it occupies during coating of the tablet with a first layer of coating material,

- 16 -

Fig. 4c is a side view of the tablet shown in Fig. 4b after coating with two layers of coating material,

Fig. 5a is a perspective view of a cylindrical crenellated shield suitable for use in another embodiment of the invention,

Fig. 5b is a side view of a tablet with the shield of Fig. 5a shown in the position it occupies during coating of the tablet with a first layer of coating material,

Fig. 5c is a side view of the tablet shown in Fig. 5b after coating with two layers of coating material,

Fig. 6a is a perspective view of a cylindrical crenellated shield suitable for use in another embodiment of the invention,

Fig. 6b is a side view of a tablet with the shield of Fig. 6a shown in the position it occupies during coating of the tablet with a first layer of coating material, and

Fig. 6c is a side view of the tablet shown in Fig. 6b after coating with two layers of coating material.

Referring firstly to Figs. 1, 2 and 2a, the apparatus shown generally comprises a source 1 of electrostatically charged powder material, a support assembly 2 for supporting tablets 3 and a voltage source 4. The support

- 17 -

assembly 2 supports a plurality of tablets and in Fig. 1 three of the tablets 3a, 3b and 3c are shown.

The source 1 of charged powder material includes a roller 1a that is electrically conducting and is connected
5 to the voltage source 4. Powder material in the source 1 is fed to the roller 1a and is charged triboelectrically during its passage to the roller 1a.

The support assembly 2 defines a plurality of tablet receiving stations at each of which a respective tablet 3a,
10 3b, 3c is received. At each station there is an electrically conducting member 5 which includes a cupped receiving part 6, on which the tablet rests, and a stem part 7. The support assembly 2 includes an electrically conducting shield assembly 8 mounted (by suitable mounts
15 not shown) just above an electrically insulating body 9 of the assembly 2. The shield assembly 8 is made of sheet metal. The shield assembly 8 has openings 19 within each of which a respective tablet 3 is received with a respective shield 10 closely surrounding but spaced from
20 the tablet 3 by a small distance (for example 0.5mm) as shown in Fig. 2a. Each shield 10 is of generally cylindrical shape, of circular cross-section and defines the openings 19. The shield assembly 8 is fabricated from sheet metal and at least the interior portions of the
25 shields 10 that closely surround the tablets 3 are coated with a layer of electrically insulating material.

Each tablet 3 has a pair of opposite domed end faces, namely a front face 12F and a rear face 12R, and also a

- 18 -

cylindrical side wall 12S, as shown in Fig. 2. The cupped receiving part 6 of the electrically conducting member 5 is shaped so that its concave lower face matches the convex rear face 12R of the tablet 3.

5 It will be noted that in Fig. 1 the tablet is shown on a bottom face of the support assembly 2. It should be understood that the tablet is held on the bottom face against the force of gravity by suitable means, for example by suction (for example, by providing air passageways
10 through the cupped receiving parts 6 and around the stem parts 7 of the conducting members 5 and connecting those passageways to the air inlet side of a vacuum pump).

The voltage source 4 applies a bias voltage to the roller 1a of the source 1 of the charged powder material
15 and also applies the same voltage to the shield assembly 8.

The electrically conducting member 5 is earthed. The bias voltage applied by the source 4 is a steady DC bias voltage with an AC voltage superimposed thereon.

In operation of the apparatus, the tablets 3 are moved
20 past the source 1 of electrostatically charged powder material. In Fig. 1 the tablet 3b is shown passing the roller 1a, (with the roller 1a and the tablet moving in the directions shown by the arrows in Fig. 1). The bias voltage generates an electric field between the roller 1a
25 and the receiving part 6 of the electrically conducting member 5. That electric field causes electrostatically charged powder at the roller 1a to be transferred across to the tablet and to coat the part of the tablet that projects

- 19 -

forwards (downwards in Figs. 1 and 2) beyond the boundary edge of the cylindrical portion 10 of the shield assembly 8. The shield assembly 8, however, provides a barrier to the powder material, preventing coating of more rearward parts of the tablet. More particularly, the shield 8 provides a physical barrier, because of its proximity to the side wall of the tablet, and also an electrostatic barrier, being at the same voltage potential as the roller 1a. Thus, the electric field, which provides the driving force for the charged powder, will be cancelled out at some point between the powder source and the shield and will be reversed in the immediate vicinity of the shield. Powder will be repelled from approaching the shield by virtue of the voltage potential of the shield and the charge on the powder.

The description above is concerned with the part of the powder coating process in which the powder is actually applied to the tablet, that being the distinctive part of the process. It will be understood, however, that there will usually be other steps in the process including in particular a step of heating the powder to fuse it and secure it to the tablet. In a case where opposite faces of a tablet are to be coated, powder may be applied to the first face, that powder fused, the tablet turned over and then powder applied to the second face and fused. Further details of other steps in the process that may be employed are given in WO 96/35516, the contents of which is incorporated herein by reference. Whilst that

- 20 -

specification shows one particular form of support assembly for supporting and conveying the tablets, it should be understood that other systems could be used. Examples of other conveying arrangements are shown in WO 98/20861 and
5 WO 98/20863, the contents of which are also incorporated herein by reference. Another possible conveying arrangement is one in which the tablets are conveyed along a path disposed in a single plane (which may be horizontal or inclined), travelling through various treatment stations
10 arranged along the path. For example, powder may be applied to one face of the tablet at a first station, the powder fused at a second station, the tablet cooled at a third station, the tablet turned over at a fourth station, powder applied to the opposite face of the tablet at a
15 fifth station, that powder fused at a sixth station and the tablet cooled at a seventh station. Suitable powder coating materials for coating the tablets are described in WO 96/34513, the contents of which is incorporated herein by reference.

20 In the illustrated embodiment the body 9 is described as electrically insulating, but it is also possible for the body 9 to be electrically conducting, provided that it is insulated from the shield assembly 8. If the body 9 is electrically conducting, then there is no longer a need to
25 provide the separate electrically conducting members 5.

Whilst in the described embodiment the shield assembly 8 and the roller 1a are maintained at the same potential and connected to the same voltage source, that

- 21 -

need not be the case. For example, the shield assembly 8 could be maintained at a potential of the same polarity as, but a different (typically smaller) magnitude from, the potential of the roller 1a.

5 The method and apparatus described above is very similar to the method and apparatus described in WO 03/061841, the contents of which are also incorporated herein by reference. Embodiments of the present invention differ from the embodiment shown in WO 03/061841 in the
10 configuration of the shields 10. Figs. 3a to 6c illustrate various different shield configurations and the different coating patterns that can be obtained by using the shields, as described in more detail below.

Fig. 3a shows a first form of shield 101 that can be
15 employed. The shield 101 may be regarded as a replacement for the shield 10 of Figs. 1 to 2A and may be connected to other shields to form a shield assembly in a similar manner to the shield 10. The shield 101 differs from the
20 cylindrical shape having a cylindrical wall 102, it is provided with a projecting portion 103 on its forwardly projecting end which faces the source of powder material. Thus the forward boundary edge of the shield 101 has a
25 projecting portion 104 defined by the forwardly projecting edge of the portion 103 and a recessed portion 105 defined by the forwardly projecting edge of the cylindrical wall 102.

- 22 -

A first layer of coating material is applied to a solid dosage form (reference 100 in Figs. 3b and 3c) with the solid dosage form 100 and the shield 101 in the positions shown in Fig. 3b in which the shield is shown shaded. During that coating process, all of the unshaded area in Fig. 3b is coated but the rearward portion of the solid dosage form and also the portion lying behind the projecting portion 103 is not coated. Consequently, a rectangular uncoated region 106 is formed on the solid dosage form.

A second coating step is then carried out with the solid dosage form placed in a shield in an inverted configuration. The shield used in this second process has a straight boundary edge as in the case of the shield 10 shown in Figs. 2 and 2A. During the second coating process, the remainder of the solid dosage form is coated with a coating that slightly overlaps the first coating, apart from in the region 106 (unshaded in Fig. 3c), almost all of which remains uncoated. Thus after both coating layers have been applied, a solid dosage form of the kind shown in Fig. 3c, having a single uncoated region 106, is obtained. It will be seen that in Fig. 3c the uncoated region is not equispaced between the end faces of the solid dosage form, but it will be understood that, by suitable altering of the relative positions of the shield 101 and the solid dosage form, it is possible to position the uncoated region midway between the end faces.

- 23 -

Fig. 4a shows a second form of shield 201 that can be employed. The shield 201 is very similar to the shield 101 and is used in a similar manner during application of a first coating layer. In Figs. 4a to 4c parts corresponding to those shown in Figs. 3a to 3c are marked by three digit reference numerals having the same last digit but 20 instead of 10 as the first two digits. The shield 201 differs from the shield 101 in that the projecting portion 203 is of triangular shape rather than a rectangular shape. As a result a triangular uncoated region 206 (that region not being visible in Fig. 4b since it is behind the projecting portion 203) is formed on the solid dosage form during application of the first layer of coating material.

The second coating step may be carried out as described with reference to Figs. 3a to 3c, in which case the final uncoated region would be triangular, but in the illustrated embodiment the second step is carried out with the solid dosage form placed the other way up and surrounded by a shield substantially the same as the shield 201 (or the shield 201 is used again). In that case, during the second coating process, the remainder of the solid dosage form is coated with a coating that slightly overlaps the first coating apart from in the region 206 where a further triangular uncoated region is created, the two triangular uncoated regions together defining a diamond-shaped uncoated region 207, as shown in Fig. 4c.

- 24 -

Fig. 5a shows a third form of shield 301 that can be employed. The shield 301 is very similar to the shield 201 and is used in the same way during application of both the first and second coating layers. In Figs. 5a to 5c parts
5 corresponding to those shown in Figs. 4a to 4c are marked by three digit reference numerals having the same last digit but 30 instead of 20 as the first two digits. The shield 301 differs from the shield 201 in that the projecting portion 303 is of semi-circular shape rather
10 than of triangular shape. As a result a semi-circular uncoated region 306 (that region not being visible in Fig. 5b since it is behind the projecting portion 303) is formed on the solid dosage form during application of the first layer of coating material and that becomes a circular
15 region 307 after application of the second layer of coating material. Of course the region formed in this way may be oval rather than circular and, if the second coating step is carried out as described with reference to Figs. 3a to 3c then the region may be semi-circular.

20 Fig. 6a shows a fourth form of shield 401 that can be employed. The shield 401 is very similar to the shield 101 and is used in the same way during application of both the first and second coating layers. In Figs. 6a to 6c parts corresponding to those shown in Figs. 3a to 3c are marked
25 by three digit reference numerals having the same last digit but 40 instead of 10 as the first two digits. The shield 401 differs from the shield 101 in that there are a plurality of projecting portions 403 evenly spaced around

- 25 -

the shield. In the illustrated embodiment the projecting portions 403 are rectangular but it will be understood that they could be another shape including one of the shapes shown in Figs. 4a and 5a. Use of the shield 401 results in a plurality of uncoated regions 406 being formed around the solid dosage form. The second coating step is then carried out as described above with reference to Figs. 3a to 3c so that, after both coating layers have been applied, a solid dosage form of the kind shown in Fig. 6c having a plurality of uncoated regions 406, is obtained.

- 26 -

Claims:

1. A method of applying coating material onto part of a side of a solid dosage form, the method including the following steps:
 - 5 providing a source of coating material and a support assembly supporting the solid dosage form, the support assembly including a shield,
arranging the solid dosage form relative to the shield with a forward boundary edge of the shield extending around
10 and closely surrounding the side of the solid dosage form, and
applying coating material to the solid dosage form from the source, the boundary edge of the shield defining a rearward limit of an exposed portion of the side of the
15 solid dosage form onto which coating material is applied,
wherein the boundary edge of the shield has projecting and recessed portions arranged such that the rearward limit of the exposed portion of the side of the solid dosage form varies around the solid dosage form.
- 20 2. A method according to claim 1, in which the shield comprises a cylindrical part defining a cylindrical opening for accommodating the solid dosage form.
3. A method according to any preceding claim, in which the boundary edge of the shield has a plurality of
25 projecting portions and a plurality of recessed portions.
4. A method according to any preceding claim, in which the boundary edge of the shield is of crenellated form.

- 27 -

5. A method according to any preceding claim, in which the projecting portion of the boundary edge is of a curved shape.

6. A method according to claim 5, in which the projecting
5 portion of the boundary edge is of part-circular shape.

7. A method according to any of claims 1 to 4, in which the projecting portion of the boundary edge is of rectangular shape.

8. A method according to any preceding claim including
10 the further step of applying further coating material to at least a part of the shielded portion of the solid dosage form.

9. A method according to claim 8, in which the further coating material is applied subsequently by a method
15 including the following steps:

providing a source of further coating material and a support assembly for supporting the solid dosage form, the support assembly including a shield,

arranging the solid dosage form relative to the shield
20 in a new arrangement with a forward boundary edge of the shield extending around and closely surrounding the side of the solid dosage form and with the solid dosage form inverted such that at least some of the portion of the side of the solid dosage form to which coating material was
25 previously applied is to the rear of the forward boundary edge of the shield and is thereby shielded, and

applying the further coating material to the solid dosage form from the source, the forward boundary edge of

- 28 -

the shield defining a rearward limit of an exposed portion of the side onto which the further coating material is applied, the rearward limit extending rearwardly as far as a previously coated region of the side in at least one position around the boundary edge but not in at least another position around the boundary edge, whereby the side of the solid dosage form in said at least another position remains uncoated.

10. A method according to claim 9, in which the boundary edge of the shield that is used when applying the further coating material has projecting and recessed portions arranged such that the rearward limit of the exposed portion of the side of the solid dosage form varies around the solid dosage form.

11. A method according to claim 10, in which the variation in the rearward limit of the further coating material applied is matched to the variation in the rearward limit of the previously applied coating material.

12. A method according to any preceding claim, in which the coating material is applied electrostatically.

13. A method according to claim 12, in which the coating material is charged.

14. A method according to claim 13, in which the solid dosage form is supported on the support assembly with a front face in the vicinity of the source of coating material and facing the source of coating material, the support assembly includes an electrically conducting member in the vicinity of the rear face of the solid dosage form,

- 29 -

the shield is electrically conducting, a potential difference is created between the source of coating material and the electrically conducting member, and the shield is maintained at a potential more similar to that of
5 the source of coating material than to that of the electrically conducting member.

15. A method according to claim 14, in which the potentials at which the electrically conducting shield and the source of powder material are maintained are of the
10 same sign.

16. A method according to claim 15, in which the potentials at which the electrically conducting shield and the source of powder material are maintained are substantially the same.

15 17. A method according to any of claims 14 to 16, in which the electrically conducting shield comprises an electrically conducting member covered by a layer of insulating material.

18. A method according to any preceding claim, in which
20 the spacing between the boundary edge of the shield and the solid dosage form is less than 1mm.

19. A method according to any preceding claim, in which a plurality of solid dosage forms are supported on the support assembly, a plurality of shields, each disposed
25 closely around a respective one of the solid dosage forms are provided and the support assembly is moved relative to the source of coating material to bring in turn each of the

- 30 -

solid dosage forms into the vicinity of the source of coating material.

20. A method according to any preceding claim, in which the coating material applied to the solid dosage form is subsequently treated to fix it on the solid dosage form.

21. A method according to claim 20 in which the treatment of the coating material to fix it on the solid dosage form includes a heating step.

22. A method according to any preceding claim, in which the solid dosage form is an oral dosage form.

23. A method according to any preceding claim, in which the solid dosage form is a pharmaceutical dosage form.

24. A method according to any preceding claim, in which the solid dosage form is a tablet.

25. A method of applying coating material onto a side of a solid dosage form, the method including the following steps:

applying a first coating layer to a forward part of the side of the solid dosage form,

20 applying a second coating layer to a rearward part of the side of the solid dosage form,

wherein the first and second coating layers overlap in at least one region of the side of the solid dosage form but are spaced apart in at least one other region of the side of the solid dosage form to leave an uncoated region between them.

26. A method according to claim 25, in which the side of the solid dosage form is of generally cylindrical shape.

- 31 -

27. A method according to claim 25 or 26, in which the side of the solid dosage form surrounded by the shield is of round shape.

28. A method according to claim 27, in which the side of
5 the solid dosage form surrounded by the shield is of substantially circular shape.

29. A method according to any of claims 25 to 28, in which the solid dosage form is of a lozenge shape.

30. A method according to any of claims 25 to 29, in which
10 the solid dosage form has domed end faces.

31. A method according to any of claims 25 to 30, in which one of the coating layers has a straight boundary edge overlapped in at least one region by the other coating layer.

15 32. A method according to any of claims 25 to 31, in which a plurality of uncoated regions are left.

33. A method according to claim 32, in which the uncoated regions are evenly spaced around the solid dosage form.

34. A method according to any of claims 25 to 33, in which
20 the or each uncoated region is of generally round shape.

35. A method according to any of claims 25 to 33, in which the or each uncoated region is of generally rectangular shape.

36. A method according to any of claims 25 to 35, in which
25 said at least one uncoated region occupies only a minor part of the perimeter of the solid dosage form.

37. A method according to any of claims 25 to 36, in which the solid dosage form is an oral dosage form.

- 32 -

38. A method according to any of claims 25 to 37, in which the solid dosage form is a pharmaceutical dosage form.
39. A method according to any of claims 25 to 38, in which the solid dosage form is a tablet.
- 5 40. A solid dosage form including a side extending around the solid dosage form and having at least two coating layers each of the layers extending around the solid dosage form with layers overlapping in at least one region and being spaced apart in at least one other region to leave an
10 uncoated region between them.
41. A solid dosage form according to claim 40, in which the side of the solid dosage form is of generally cylindrical shape.
42. A solid dosage form according to claim 40 or 41, in
15 which the side of solid dosage form is of round shape.
43. A solid dosage form according to claim 42, in which the side of the solid dosage form is of substantially circular shape.
44. A solid dosage form according to any of claims 40
20 to 42, in which the solid dosage form is of a lozenge shape.
45. A solid dosage form according to any of claims 40 to 44, in which the solid dosage form has domed end faces.
46. A solid dosage form according to any of claims 40
25 to 45, in which one of the coating layers has a straight boundary edge overlapped in at least one region by the other coating layer.

- 33 -

47. A solid dosage form according to any of claims 40 to 46, in which a plurality of uncoated regions are left.

48. A solid dosage form according to claim 47, in which the uncoated regions are evenly spaced around the solid

5 dosage form.

49. A solid dosage form according to any of claims 40 to 48, in which the or each uncoated region is of generally round shape.

50. A solid dosage form according to any of claims 40 to 48, in which the or each uncoated region is of generally rectangular shape.

51. A solid dosage form according to any of claims 40 to 50, in which said at least one uncoated region occupies only a minor part of the perimeter of the solid dosage form.

52. A solid dosage form according to any of claims 40 to 51, in which the solid dosage form is an oral dosage form.

53. A solid dosage form according to any of claims 40 to 52, in which the solid dosage form is a pharmaceutical dosage form.

54. A solid dosage form according to any of claims 40 to 53, in which the solid dosage form is a tablet.

55. An apparatus for applying coating material onto part of a side of a solid dosage form, the apparatus including:
a source of coating material, and
a support assembly for supporting the solid dosage form in a position where the part of the side wall onto

- 34 -

which coating material is to be applied is able to receive the coating material,

wherein the support assembly includes a shield for extending around and closely surrounding the side wall of the solid dosage form, the shield having a boundary edge for defining a rearward limit of an exposed portion of the side of the solid dosage form onto which coating material is to be applied, the boundary edge having projecting and recessed portions arranged such that the rearward limit of the exposed portion of the side of the solid dosage form varies around the solid dosage form.

56. An apparatus according to claim 55, in which the shield comprises a cylindrical part defining a cylindrical opening for accommodating the solid dosage form.

57. An apparatus according to claim 55 or 56, in which the boundary edge of the shield has a plurality of projecting portions and a plurality of recessed portions.

58. An apparatus according to any of claims 55 to 57, in which the boundary edge of the shield is of crenellated form.

59. An apparatus according to any of claims 55 to 58, in which the projecting portion of the boundary edge is of a curved shape.

60. An apparatus according to claim 59, in which the projecting portion of the boundary edge is of part-circular shape.

- 35 -

61. An apparatus according to any of claims 55 to 58, in which the projecting portion of the boundary edge is of angular shape.

62. An apparatus according to claim 61, in which the
5 projecting portion of the boundary edge is of triangular shape.

63. An apparatus according to claim 61, in which the projecting portion of the boundary edge is of rectangular shape.

10 64. An apparatus according to any of claims 55 to 63, in which the source of coating material is a source of electrically charged coating material.

65. An apparatus according to claim 64, in which the support assembly is arranged to support the solid dosage
15 form with a front face in the vicinity of the source of coating material and facing the source of coating material, in which the support assembly includes an electrically conducting member in the vicinity of the rear face of the solid dosage form, in which the shield is electrically
20 conducting, and in which means are provided for creating a potential difference between the source of coating material and the electrically conducting member and for maintaining the shield at a potential more similar to that of the source of coating material than to that of the electrically
25 conducting member.

66. An apparatus according to claim 65, in which the electrically conducting shield comprises an electrically

- 36 -

conducting member covered by a layer of insulating material.

67. An apparatus according to any of claims 55 to 66, in which the support assembly is suitable for supporting a plurality of solid dosage forms and includes a plurality of shields each arranged to be disposed closely around a respective one of the solid dosage forms.

68. An apparatus according to any of claims 55 to 67, in which the support assembly is mounted for movement relative to the source of coating material.

1/6

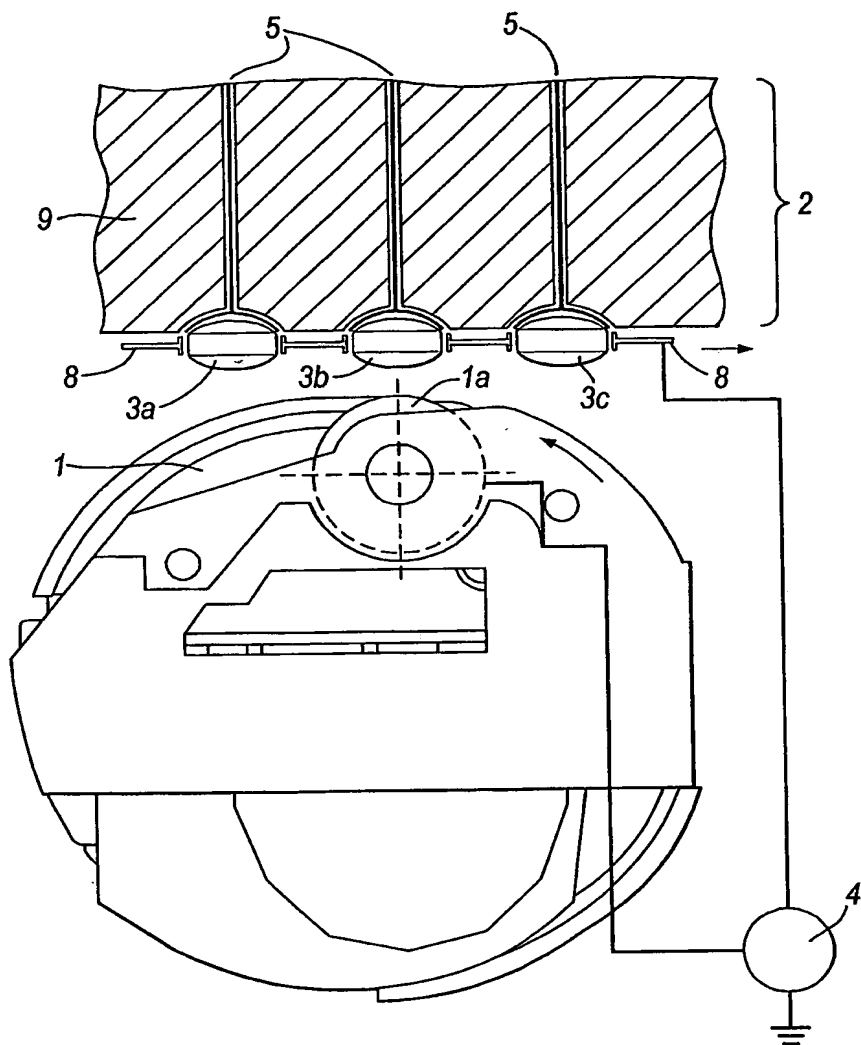


Fig. 1

2/6

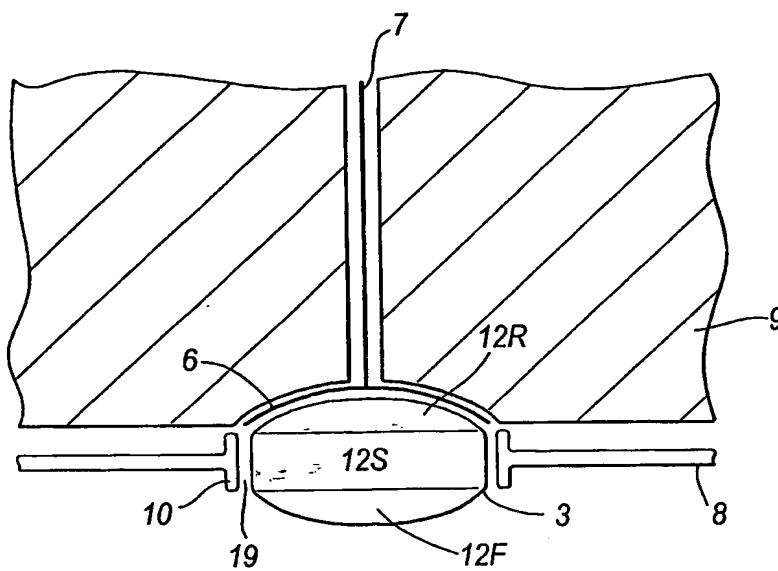


Fig. 2

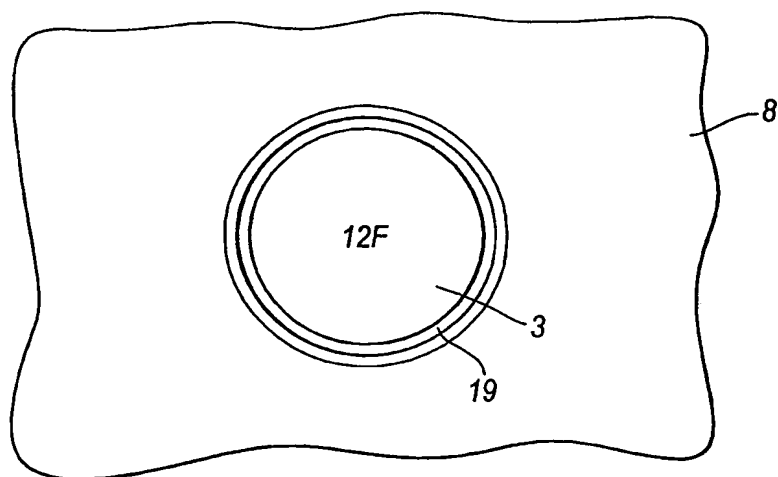


Fig. 2A

3/6

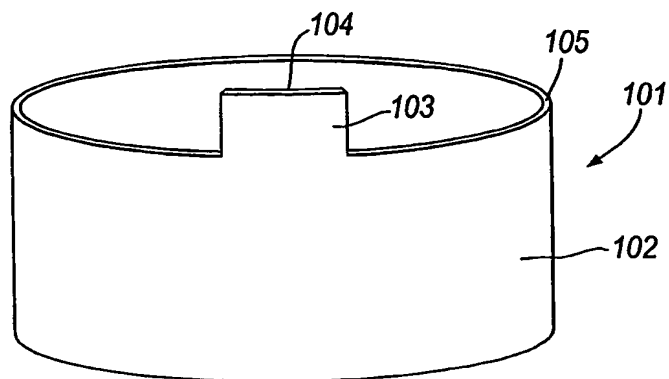


Fig. 3a

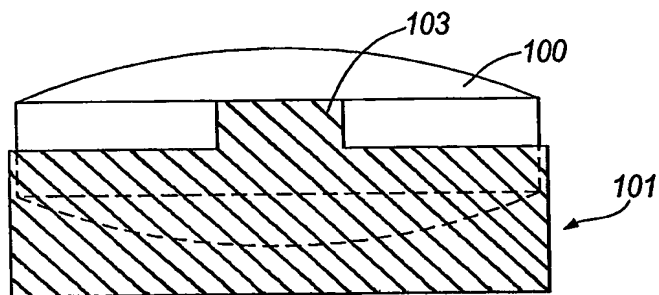


Fig. 3b

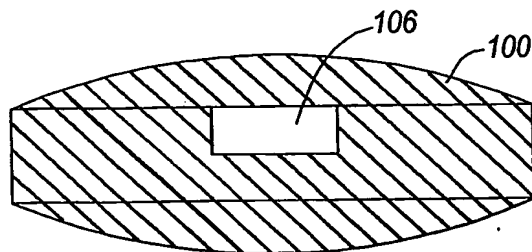


Fig. 3c

4/6

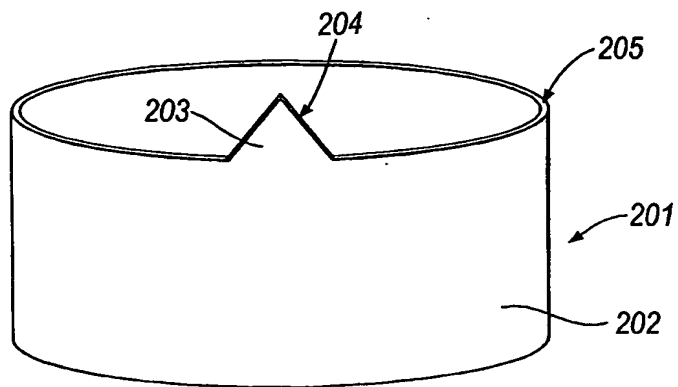


Fig. 4a

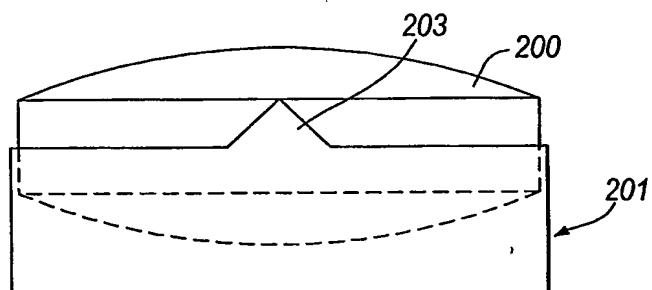


Fig. 4b

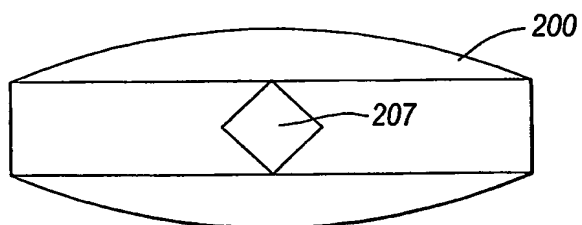


Fig. 4c

5/6

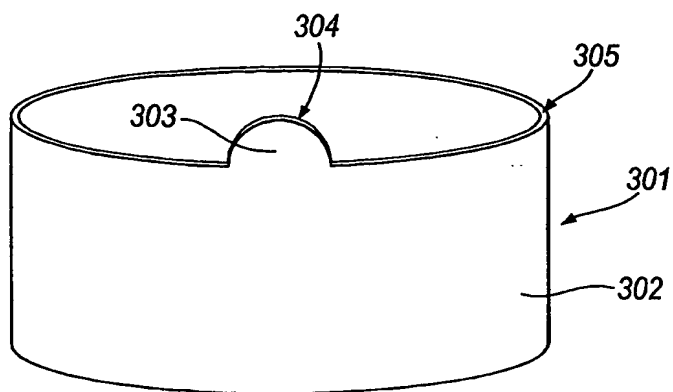


Fig. 5a

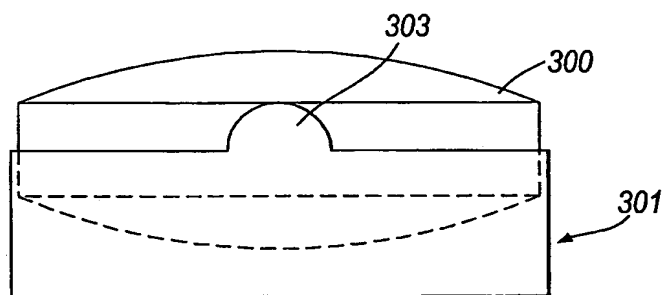


Fig. 5b

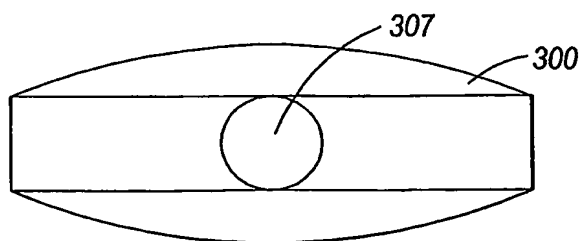


Fig. 5c

6/6

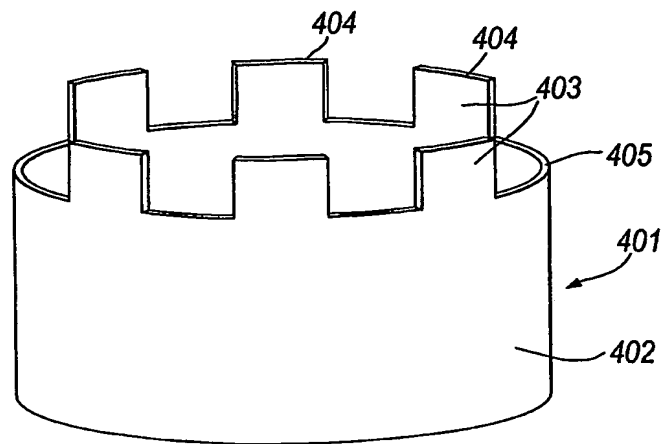


Fig. 6a

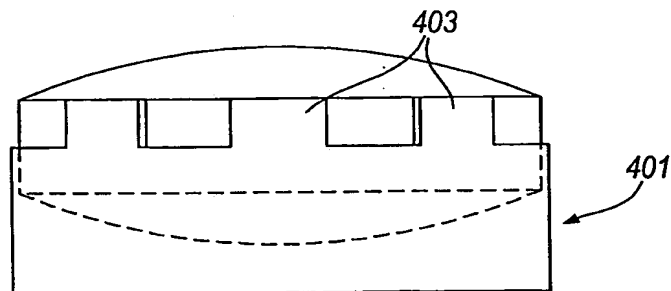


Fig. 6b

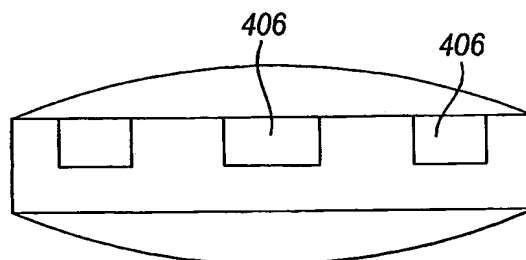


Fig. 6c